REMARKS

DISCUSSION OF SPECIFICATION

In response to the objection, the CROSS-REFERENCE TO RELATED APPLICATIONS has been amended to include to include the missing serial numbers Furthermore, minor typographical informalities have been corrected. In particular, on page 16, line 19, "**424**and" has been replaced with --**424** and--, and on page 19, line 23, "patient's" has been replaced with --patients--. Acceptance of the amended specification is respectfully requested.

DISCUSSION OF CLAIMS

In the Office Action, claim 6 is rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

In the Office Action, claims 1, 3, 5, 6, 7, 10-18, 24, and 26 are rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Application Publication No. 2002/0193697 to Cho et al.

In the Office Action, claims 2, 4, 8, 9, 19-23, and 25 are rejected under 35 U.S.C. §102(e) or, in the alternative, under 35 U.S.C. §103(a) as obvious over Cho et al.

In response thereto, claim 26 has been cancelled, claims 1-3, 5, 6, 8-12, 15, 17-19, 21, 22, and 24 have been amended, and new claims 27-30 have been added. Accordingly, claims 1-25 and 27-30 are now pending.

Preliminary Matter

In response to the rejection under 35 U.S.C. §112, second paragraph, the following amendments have been made:

claim 6, line 1, "6" has been replaced with --5--; and

claim 6, line 2, "abnormal breathing pattern is indicative of" has been replaced with --second sensor detects--.

Independent Claim 1

Claim 7 recites an implantable cardiac stimulation device comprising a control circuit that is responsive to detection of a potential sleep apnea condition to control one or more pulse generators to pace at an overdrive pacing rate based on the intrinsic heart rate to prevent sleep apnea.

The Cho et al. reference discloses a method and apparatus for detecting and treating sleep apnea. In one embodiment, the method includes gathering information from an implantable sensor device for detecting sleep apnea, extracting an average cycle length and a frequency of at least one of Cheyne-Stokes respiration and periodic breathing based upon the information gathered from the implantable sensor device, performing diagnostics and decision on the average cycle length and the frequency to form results, and delivering therapy in response to the results of the diagnostic to terminate sleep apnea.

The Cho et al. reference does not disclose or suggest a control circuit that is responsive to detection of a potential sleep apnea condition to control the one or more pulse generators to pace at an overdrive pacing rate based on the intrinsic heart rate to prevent sleep apnea. In the Cho et al. reference, therapy is provided to terminate sleep apnea whereas claim 1 of the present application is directed to preventing sleep apnea.

Accordingly, it is respectfully submitted that claim 1 is in condition for allowance.

Dependent Claims 2, 4, 8, and 9

Claims 2, 4, 8, and 9 depend from claim 1 and are similarly patentable. Accordingly, it is respectfully submitted that these claims are in condition for allowance.

Independent Claim 12

Claim 12 recites an implantable cardiac stimulation device comprising a sleep apnea determination device that is operative to determine when a potential sleep apnea condition exits, and that is responsive to the potential sleep apnea condition to control circuitry to generate pacing pulses at an overdrive pacing rate to prevent sleep apnea.

For at least the same reasons discussed above with regards to claim 1, it is respectfully submitted that claim 12 is in condition for allowance.

Dependent Claims 13 and 14

Claims 13 and 14 depend from claim 12 and are similarly patentable. Accordingly, it is respectfully submitted that these claims are in condition for allowance.

Independent Claim 19

Claim 19 recites a method of operating an implantable cardiac stimulation device comprising generating overdrive pacing pulses at an overdrive pacing rate in response to determining a potential sleep apnea condition, wherein the overdrive pacing rate is based on an intrinsic heart rate to prevent sleep apnea.

For at least the same reasons discussed above with regards to claim 1, it is respectfully submitted that claim 19 is in condition for allowance.

Dependent Claims 20 and 23

Claims 20 and 23 depend from claim 19 and are similarly patentable. Accordingly, it is respectfully submitted that these claims are in condition for allowance.

Independent Claim 24

Claim 24 recites an implantable cardiac stimulation device comprising means for overdrive pacing the heart at a rate based on the intrinsic heart rate in response to detection of a potential sleep apnea condition to prevent sleep apnea.

For at least the same reasons discussed above with regards to claim 1, it is respectfully submitted that claim 24 is in condition for allowance.

Dependent Claim 25

Claim 25 depends from claim 24 and is similarly patentable. Accordingly, it is respectfully submitted that claim 25 is in condition for allowance.

Independent Claim 27

Claim 27 recites an implantable cardiac stimulation device comprising a control circuit that is responsive to detection of a potential sleep apnea condition to control one or more pulse generators to dynamically overdrive the intrinsic heart rate. In accordance with the specification (see pages 27-29), one technique for overdrive pacing involves tracking of atrial intrinsic activity and generating pacing pulses in the atrium at a rate that exceeds the intrinsic atrial rate. When a P-wave is detected, the stimulation device increases the pacing rate by a small amount to induce pacing but not so greatly that the heart rte is substantially elevated. Over multiple cardiac cycles, the stimulation device tracks atrial pacing and any intrinsic atrial depolarization in a track cardiac cycle action and uniformly decrements the atrial pacing rate in an update atrial rate action, both actions being repeated in a loop. The track cardiac cycle action senses atrial signals and delivers an atrial pacing pulse unless inhibited by an intrinsic atrial depolarization. Generally, the track cardiac cycle action monitors whether the cardiac cycles are paced or inhibited and permits the pacing rate to be reduced for cycles that are not inhibited. Once a cycle is inhibited, the pacing rate is held constant

at a base overdrive rate and the number of cycles is counted between inhibited cycles. In one example, the base overdrive rate is set to the pacing rate at which the inhibited cycle occurs. Until the inhibited cycle, the update atrial rate action reduces the pacing rate by the preselected decrement such as a rate decrement, for example 2 bpm, or an interval length increment, for example 15 msec. The pacing rate may be decreased for each cardiac cycle or may be decreased in steps with the individual steps lasting for a selected number of cardiac cycles. The update atrial action resets the pacing rate to the assured overdrive rate if warranted by too frequent inhibited cycles.

The Cho et al. reference discloses the termination of sleep apnea by overdrive pacing at a fixed rate which is faster than the mean nocturnal heart rate. For example, the heart may be overdrive paced at a rate which is 15 bpm faster than the mean nocturnal hear rate. As such, the overdrive pacing rate is fixed whereas claim 27 recites dynamically overdriving the intrinsic heart rate.

Accordingly, it is respectfully submitted that claim 27 is in condition for allowance.

Dependent Claims 3, 5, 6, 10, 11, and 28

Claims 3, 5, 6, 10, 11 and 28 depend from claim 27 and are similarly patentable. Accordingly, it is respectfully submitted that these claims are in condition for allowance.

Independent Claim 29

Claim 29 recites an implantable cardiac stimulation device comprising a sleep apnea determination device that is operative to determine when a potential sleep apnea condition exists, and that is responsive to the potential sleep apnea condition to control circuitry to generate pacing pulses at a dynamic overdrive pacing rate.

For at least the same reasons discussed above with regards to claim 27, it is respectfully submitted that claim 29 is in condition for allowance.

Dependent Claims 15-18

Claims 15-18 depend from claim 29 and are similarly patentable. Accordingly, it is respectfully submitted that these claims are in condition for allowance.

Independent Claim 30

Claim 30 recites a method of operating an implantable cardiac stimulation device comprising generating dynamic overdrive pacing pulses at a dynamic overdrive pacing rate in response to determining a potential sleep apnea condition, wherein the dynamic overdrive pacing rate is based on an intrinsic heart rate.

For at least the same reasons discussed above with regards to claim 27, it is respectfully submitted that claim 30 is in condition for allowance.

Dependent Claim 22

Claim 22 depends from claim 30 and is similarly patentable. Accordingly, it is respectfully submitted that claim 22 is in condition for allowance.

//

//

//

//

//

//

//

CONCLUSION

In light of the above claim amendments and remarks, it is respectfully submitted that the application is in condition for allowance, and an early notice of allowance is requested.

Respectfully submitted,

3/1/04
Date

Ronald S. Tamura
Ronald S. Tamura, Reg. No. 43,179
Patent Attorney for Applicant

Pacesetter, Inc.
15900 Valley View Court
Sylmar, CA 91392-9221
818/493-3157
818/362-4795 (fax)